REMARKS

By this amendment, claims 2 and 3 are canceled and claim 1 is revised to place this application in immediate condition for allowance. Currently, claims 1 and 4-15 are before the Examiner for consideration on their merits.

First, claim 1 is revise by incorporating the limitations of claims 2 and 3 and disclosure from page 4, lines 3-7. The Examiner should understand that claim 1 parallels claim 1 of the corresponding European application. In this regard, the Examiner should also note WO/2002/35986, which was cited by Applicants, and the fact that this reference was used by the European Examiner in the European prosecution.

Second, Applicants traverse the rejection of claims 2 and 3 based on United States Published Patent Application No. 2004/0127767 to Fleener when combined with United States Patent No. 6,902,528 to Garibaldi et al. (Garibaldi) and United States Patent No. 4,971,034 to Doi.

In review, the Examiner cites Fleener as an apparatus for puncturing or otherwise manipulating human or animal tissue or organs comprising at least one guide device for instance in the form of a rigid or flexible tube,. at least one penetrating element which is guided within the guide device and which is displaceable forward and backward and rotatable within this guide device by a control unit. Fleener also discloses a partial vacuum source generating a partial vacuum and a suction head that is fitted with at least one recess having a lateral aperture.

The Examiner admits that Fleener does not teach the claimed attachment detection device and display and cites Garibaldi as teaching such a device. The

Examiner concludes that it would be obvious to employ the attachment detection system of Garibaldi in the device of Fleener.

Fleener discloses an endoscopic capsule adapted for selective attachment to the distal end portion of an endoscopic device. The capsule is designed for insertion with an interconnected endoscopic device into a patient body to provide an open space in front of the distal end of the endoscopic device thereby improving a surgeon's field of vision as well as proving a space in which to manipulate medical instruments within the patient body.

According to this, it is an objective of Fleener to provide an apparatus and a method that facilitates the performance of endoscopic medical procedures. In particular, it is an object of Fleener to provide an apparatus and a method that facilitates performing endoscopic medical procedures via an approach that is compatible with existing endoscopic devices.

To solve this problem, the capsule includes a housing for selective attachment to a distal end of an endoscopic device having an internal chamber and two apertures.

A first aperture extends through said housing to said internal chamber for receiving one or more medical instruments from the endoscopic device. The instruments are positionable through a tube member, to have operative access to the internal chamber. In addition, light sources and/or imaging devices may illuminate and image the internal chamber.

A second aperture extends through the housing to the internal chamber for providing access to patient tissue disposed adjacent to said end cap during an

endoscopic procedure. For example, one or more endoscopic instruments may be selectively advanceable and/or retractable through the second aperture to engage the patient tissue disposed outside the housing.

Alternatively, patient tissue may be disposed through the second aperture allowing for tissue engagement/manipulation within the internal chamber of the housing. For this purpose, a lumen in the tube member may be a vacuum port operable to pull a portion of the patient tissue through the second aperture into the internal chamber, wherein it may be selectively engaged by one or more endoscopic instruments.

Fleener is no more pertinent to the invention that the prior art cited in the application in the form of United States Patent No. 5,972,103 to Schmidt and United States Patent No. 5,931,810 to Grabek.

The problem with this prior art is that attachment detection is a precondition for successfully puncturing or any other manipulation because there is a great danger to injure the critical organs or tissues during manipulation, for instance, the cardiac muscle.

Based on the state of the art and the problem noted above, the invention creates an apparatus that meets the preconditions of successful puncture or other manipulation of human or animal tissue.

This objective is realized in that tissue attachment at the appropriate site of the apparatus of the invention is detected by an attachment detection system and is displayed by a display unit.

Garibaldi does not teach the detection system of the invention and, in fact, has no bearing on the invention.

Garibaldi provides an apparatus for magnetically controlling endoscopes, and in particular to a method and apparatus for magnetically controlling endoscopes in body lumens and cavities. This magnetically navigable endoscope system comprises an endoscope with a magnetic body, a component in the endoscope which transmits an image associated with the endoscope's distal end, a display component for displaying the image, an input device, a computer with image processing software and a magnetic field generating apparatus for generating a magnetic field to orient the body and thus the distal end of the endoscope.

The endoscope construction can be similar to a standard endoscope without articulation wires. The magnetic body is contained in the distal segment of the endoscope to orient the endoscope upon the application of an external magnetic field. The video image, e.g., an optical, ultrasound or infrared image, from the endoscope is sent to a computer with image processing software, which provides general graphic overlays, i.e., lines and text, and image rotation functions.

An input device such as a controller connected to the computer allows a physician to specify the change in deflection angle of the endoscope's distal end. As the controller is moved to the left, right, forward, or backward positions, the computer senses the controller's position and accordingly, processes a change in the magnetic field direction. The computer then causes the magnetic field generating apparatus to apply the new magnetic field direction.

Therefore, the method of magnetically navigating endoscopes of Garibaldi comprises specifying the direction to orient the endoscope using a variety of input devices and user interfaces, while the endoscope is manually or automatically advanced in the body lumen or cavity.

Consequently, the magnetically navigable endoscope system of Garibaldi allows a health care professional to quickly and intuitively navigate the endoscope through the body lumens and cavities. In a preferred embodiment, the system interface allows the health care professional to move the endoscope through the body without having to get involved in directly controlling the magnetic field direction and strength. This is achieved by allowing the physician to directly visualize the body lumen or cavity in which the endoscope is located and navigate based on the viewed image.

Based on the above, it can be said that Garibaldi does have a detection system for remotely determining the orientation of the medical device during operation. However, this is not a **tissue attachment** detection system and display as is required in claim 1.

The system of Garibaldi comprises an endoscope, a light source connected to the endoscope to provide light to illuminate the body lumen or cavity surrounding the distal end of the endoscope, an imaging device, for example, a camera, for capturing images of the body lumen or cavity surrounding the distal end of the endoscope, and a computer for processing the image captured by the imaging device and displaying the imaging on a display. Instead of a camera for capturing optical images, the imaging

device could be an ultrasonic imaging device or an infrared imaging device, or some other suitable imaging device.

The computer is connected to the controller for receiving input for controlling the endoscope and processing the input to create an output control signal to the magnetic field generating device to control the magnetic field applied to the distal end of the endoscope to move (orient and/or advance) the distal end of the endoscope in the desired direction.

The magnetically navigable endoscope system can also include one or more sensors, triggered by contact with an anatomical structure such as the wall of the body lumen or cavity. These sensors, for example, a spring contact, can be distributed around the distal end of the endoscope to sense contact anywhere around the circumference of the distal end of the endoscope.

Therefore, the device of Garibaldi is only an endoscope where the distal end is magnetic and which can be moved by changing a magnetic field around the tip of the endoscope within a patient. The image and the sensors are only used to remotely determine the orientation of the distal end of the endoscope. The navigation is based on viewed images.

The system of Garibaldi has nothing to do with the present invention. The system of Garibaldi cannot be used to detect a tissue attachment at an appropriate site of a guide device comprising a suction head that is fitted with at least one recess having a lateral aperture. The optic sensor and the ultrasonic sensor of Garibaldi are

only used to obtain information about the orientation of the medical device and not of any tissue surrounding the endoscope.

Therefore, it would not be obvious to employ the system of Garibaldi in the device of Fleener since Garibaldi is not able to determine the orientation of the tissue absorbed in the suction head of the invention. The detection system of Garibaldi is only able to determine the orientation of the medical device; it has nothing to do with tissue attachment at the appropriate site.

Since Garibaldi is not even a detection system, it cannot be considered to be the same as that claimed. This means that even if the Examiner were to insist that Garibaldi could be combined with Fleener, the features of claim 1 are still not present and a *prima facie* case of obviousness does not exist.

In addition, one of skill in the art would have no reason to employ the sensors of Garibaldi in the device of Fleener. These sensors are used in connection with the magnetically navigable endoscope of Garibaldi. Fleener is unrelated to such a magnetically navigable endoscope. Why would one of skill in the art use the sensors of Garibaldi, which are designed to be used with the magnetically navigable distal end of an endoscope, in the device of Fleener, which is not a magnetically navigable endoscope. There is no reason for doing so and the Examiner is using hindsight to formulate the rejection.

Doi does not make up for the failings of Garibaldi. Doi merely teaches the use of pressure in an endoscope. Doi still fails to teach or suggest the detection of tissue

attachment as defined in claim 1. Therefore, even if Doi were combined with Fleener and Garibaldi, the invention of claim 1 still does not exist.

In addition, Applicants argue that the rejection lacks the proper reason to modify Fleener/Garibaldi using the teachings of Doi. Claim 1, as amended, requires a specific vacuum source, a specific calibration or adjustment based on pressure measurement when the suction head is closed, and that the attachment detection system comprises the pressure detector for measuring a pressure or change in pressure. In the rejection, the Examiner alleges that Doe has a pressure sensor for measuring pressure change. The Examiner's reasoning for relying on Doi is "to determine the orientation of the medical device." In Doi, suction is controlled by pressure as is gas pressure in the stomach. This has nothing do with orientation of the medical device and the Examiner's reasoning for relying on Doi is improper and this taints the rejection. In fact, the prior art cited against claims 2 and 3 does not obviate claim 1 in its amended form.

The arguments above demonstrate that the rejection based on Fleener, Garibaldi, and Doi does not establish a prima facie case of obviousness against claim 1. Further, the remaining claims are patentable based on their dependency on claim 1.

Lastly, Applicants submit that the claims are also patentable over the reference cited above that was used in the corresponding European application.

Accordingly, the Examiner is requested to examine this application and pass all pending claims onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is invited to contact the undersigned.